

REMARKS

By this Amendment, claims 1, 2, 15, 17 and 21 have been amended, and claims 23 and 24 have been cancelled without prejudice or disclaimer. No claims have newly added. Support for the instant amendments may be found throughout the as-filed specification. No new matter has been added. Thus, claims 1-5, 7-11, 15-19, 21, 22, and 25-27 are pending, of which claims 8-11 and 17-19 have been previous withdrawn from consideration.

In light of the foregoing amendments and the following remarks, allowance of all the claims pending is requested.

REJECTIONS UNDER 35 U.S.C. § 112

A. Claims 1, 15 and 21 were rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement. In particular, the Examiner asserts that “the new recitation that ‘at least a portion of an exposed back surface of the septum is in contact with at least a portion of the circulating first fluid redirected by the circulating plate,’ appears to be new matter as the limitation is not stated or described in the specification at all.” Office Action, page 3. Applicant respectfully disagrees with this rejection for *at least* the reasons presented in the Pre-Appeal Brief Request for Review filed July 21, 2010 (hereafter “Pre-Appeal Brief Request”), and incorporated herein by reference.

In the Interview Summary mailed September 21, 2010 (hereafter “Interview Summary”), the Examiner later *acknowledges* that it was the Panel's decision that the aforementioned limitation is “not new matter as the limitation is discussed with respect to Figure 14.” Applicant therefore submits that the §112, first paragraph, rejection should be overturned because, as *acknowledged*, that subject matter is supported by at least Figure 14 of Applicant's specification.

However, in the Interview Summary, the Examiner further asserts that "there is an enablement issue as the claim is now directed to a non-elected embodiment of Figure 14.

Originally, Applicant elected the embodiment of Figures 2-5. In Figure 4, the first fluid does not contact the back surface of the septum and only contacts the slit surface of the septum." Applicant disagrees.

The Examiner is apparently confusing Restriction Practice with the Enablement requirement. These are two separate issues. To the extent the species shown in Figure 14 was not elected, that does not mean that Figure 14 is not part of an enabling disclosure. Indeed, any part of the specification can support an enabling disclosure, even a background section that discusses, or even disparages, the subject matter disclosed therein. *Callicrate v. Wadsworth Mfg., Inc.*, 427 F.3d 1361, 77 USPQ2d 1041 (Fed. Cir. 2005).

In any event, paragraphs 43-44 of the Specification – which describe Figure 4 – specifically disclose:

The fluid flown up to the regions 1141 and 1142 is bounced back by the septum 130, etc., and drops toward the groove 1442, which is a clearance between the circulating portion 140 and the wall surface of the inner cavity 114, and then passes sequentially through the grooves 1442, 1443, and 1421 to the narrow tube portion 117, and thus eventually infused to a patient (FIG. 4).

Thus, by providing the circulating portion 140, replacement of the fluid that remains in the regions 1141 and 1142 where conventionally the fluid has been hardly replaced can be promoted. The circulating portion 140 has a preferable effect also in the case where the fluid flows from the narrow tube portion 117 side of the channel tube unit 110, for example, in the case where blood is extracorporeally circulated. For example, in the case of extracorporeal circulation, stagnation and coagulation of blood can be prevented by circulating the blood that has been flown in from the narrow tube portion 117 side to the septum 130 side. In this case, the circulating portion 140 serves to circulate the fluid that has been flown in from the narrow tube portion 117 to the septum 130 side, and guide the fluid to the top portion of the luer or the like.

[emphasis added].

Thus, from the above passages, Applicant submits that it is quite clear that the subject matter of claims 1, 15 and 21 is described with respect to the elected species also.

For *at least* the foregoing reasons, Applicant submits that the Examiner's assertions are without merit, because the claimed subject matter is adequately and amply supported by the Specification. Thus, the rejection of claims 1, 15 and 21 under § 112, ¶ 1, is improper and should be withdrawn.

B. Claims 1, 15 and 21 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention.

The test for definiteness under 35 U.S.C. 112, second paragraph, is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986) (emphasis added).

Applicant submits that one skill in the art having read Applicant's Specification would understand what is meant by "*an exposed back surface of the septum.*" (see, e.g., the discussion above with respect to the § 112, ¶ 1 rejection). Moreover, the claims themselves specifically recite that "a portion of an exposed back surface of the septum is in contact with at least a portion of the first circulating fluid." (emphasis added). As such, it is quite clear from the plain language of the claims, what element is exposed to the a portion of the back surface of the septum.

For *at least* the foregoing reasons, Applicant submits that the Examiner's assertions are without merit, as the claims are definite and clear on their face. Thus, the rejection of claims 1, 15 and 21 under § 112, ¶ 2, should be withdrawn.

REJECTIONS UNDER 35 U.S.C. § 103

A. Claims 1-3, 7, 15, 16, 21-23 and 25-27 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Larkin (U.S. Patent No. 5,961,497), in view of Cote (U.S. Patent No. 5,775,671).

Applicant respectfully disagrees with this rejection for *at least* the reasons presented in the Pre-Appeal Brief Request, and incorporated herein by reference. However, solely in an effort to expedite prosecution and in no way acquiescing to the propriety of these rejections, Applicant has amended independent claims 1, 15 and 21 to further clarify aspects of the claimed invention.

Amended independent claim 1 recites, *inter alia*, the features of:

wherein an annular protrusion is formed on the inner cavity of the channel tube such that the plate portion of the circulating member is engaged between the annular protrusion and a step formed between the inner cavity and the narrow tube portion such that an axial position of the circulating member in the channel tube unit is substantially restricted when the tube member is inserted into or pulled out of the slit.

[emphasis added].

Applicant submits that the cited portions of Larkin and Cote, whether taken alone or in combination, do not disclose, teach or otherwise render obvious at least the above-emphasized features of independent claim 1.

For example, (i) the Examiner *acknowledges* that Larkin does not teach a circulating plate, and (ii) to the extent that the Examiner relies upon the actuator 50 of Cote to allegedly teaches a circulating plate, the axial position of the actuator 50 is not restricted. Rather, when the luer tip 70 is pressed upon the actuator 50 in the apparatus of Cote, the actuator 50 moves downward causing the valve disc 40 to separate from the valve seat 22 thus opening the valve. [See Cote, col. 6, lines 1-5; see also FIG. 5B].

As such – not only does Cote not teach or suggest the claimed invention – but to modify Cote to resist axial motion of the actuator 50 in the manner that amended claim 1 recites would render the valve of Cote inoperable. Indeed, if proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *See In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Thus, for *at least* the foregoing reasons, Applicant submits that Larkin and Cote, whether taken alone or combination, fail to disclose, teach or otherwise render obvious each and every feature of amended claim 1. As such, claim 1 is clearly patentable over Larkin and Cote. Claims 15 and 21 recite similar features as claim 1. Therefore, the arguments presented for claim 1 above, similarly apply to claims 15 and 21 as well. Claims 2, 3, 7, 16 and 22 ultimately depend from claims 1, 15 and 21, and are patentable for the same reasons as claims 1, 15 and 21 as well as for their additional recitations. Accordingly, the rejection of claims 1-3, 7, 15, 16, 21 and 22 under 35 U.S.C. § 103(a) over Larkin in view of Cote should be withdrawn and the claims be allowed. Claim 23 has been cancelled and thus the rejection thereof is moot.

B. Claims 4, 5 and 24 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Larkin and Cote, as applied to claim 2 above, and further in view of Arnett (U.S. Patent No. 5,817,069). Applicant disagrees with this rejection.

As discussed above, the cited portions of Larkin and Cote do not disclose, teach or otherwise render obvious each and every feature of claim 1.

Even assuming *arguendo* that the combination of Larkin, Cote and Arnett is proper (which Applicant does not concede), Applicant submits that Arnett does not overcome the deficiencies of Larkin and, Cote as set forth above either.

Accordingly, the rejection of claims 4, 5 under 35 U.S.C. § 103(a) over Larkin and Cote, as applied to claim 2 above, and further in view of Arnett should be withdrawn and the claims be allowed. Claim 24 has been cancelled and thus the rejection thereof is moot.

CONCLUSION


Having addressed each of the foregoing rejection, it is respectfully submitted that a full and complete response has been made to the outstanding Office Action and, as such, the application is in condition for allowance. Notice to that effect is respectfully requested.

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

If an extension of time is necessary to prevent abandonment of this application, then such an extension of time is hereby petitioned for under 37 C.F.R. §1.136(a). Any fees required (including fees for net addition of claims) are hereby authorized to be charged to **Deposit Account No. 033975** (Ref. No. **061069-0318680**).

Date: **October 29, 2010**

Respectfully submitted,

By: 
Eric B. Compton
Registration No. 54,806

Customer No.: 00909

Pillsbury Winthrop Shaw Pittman LLP
P.O. Box 10500
McLean, Virginia 22102

Direct: (703) 770-7721
Main: (703) 770-7900
Fax: (703) 770-7901